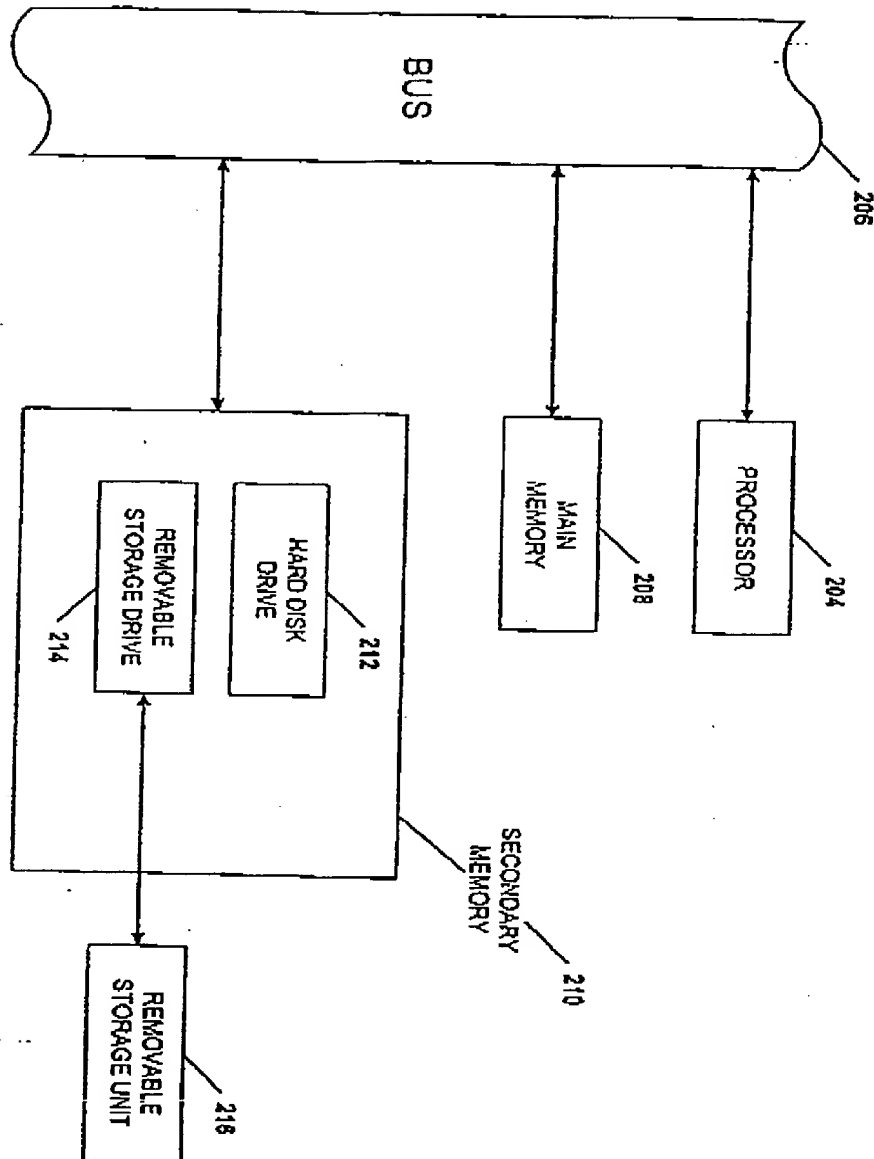
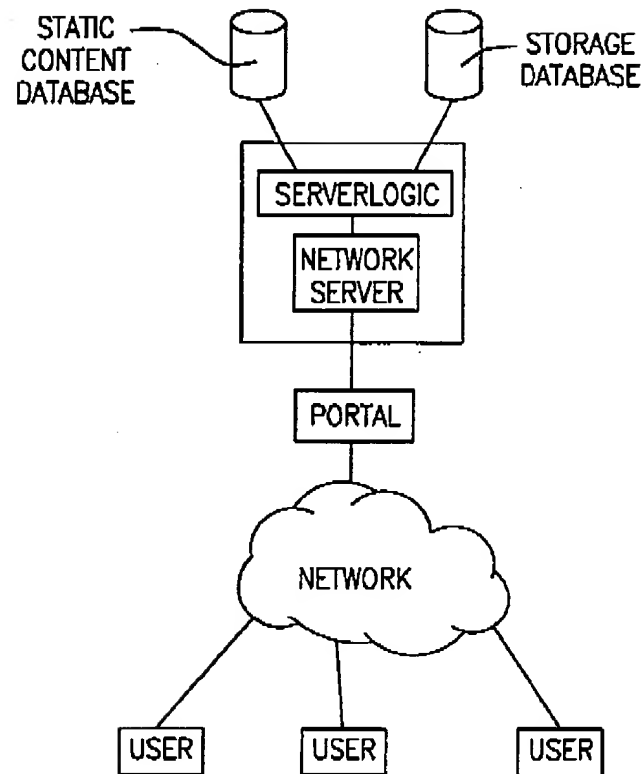




BEST AVAILABLE COPY

FIG. 1



*FIG. 2*

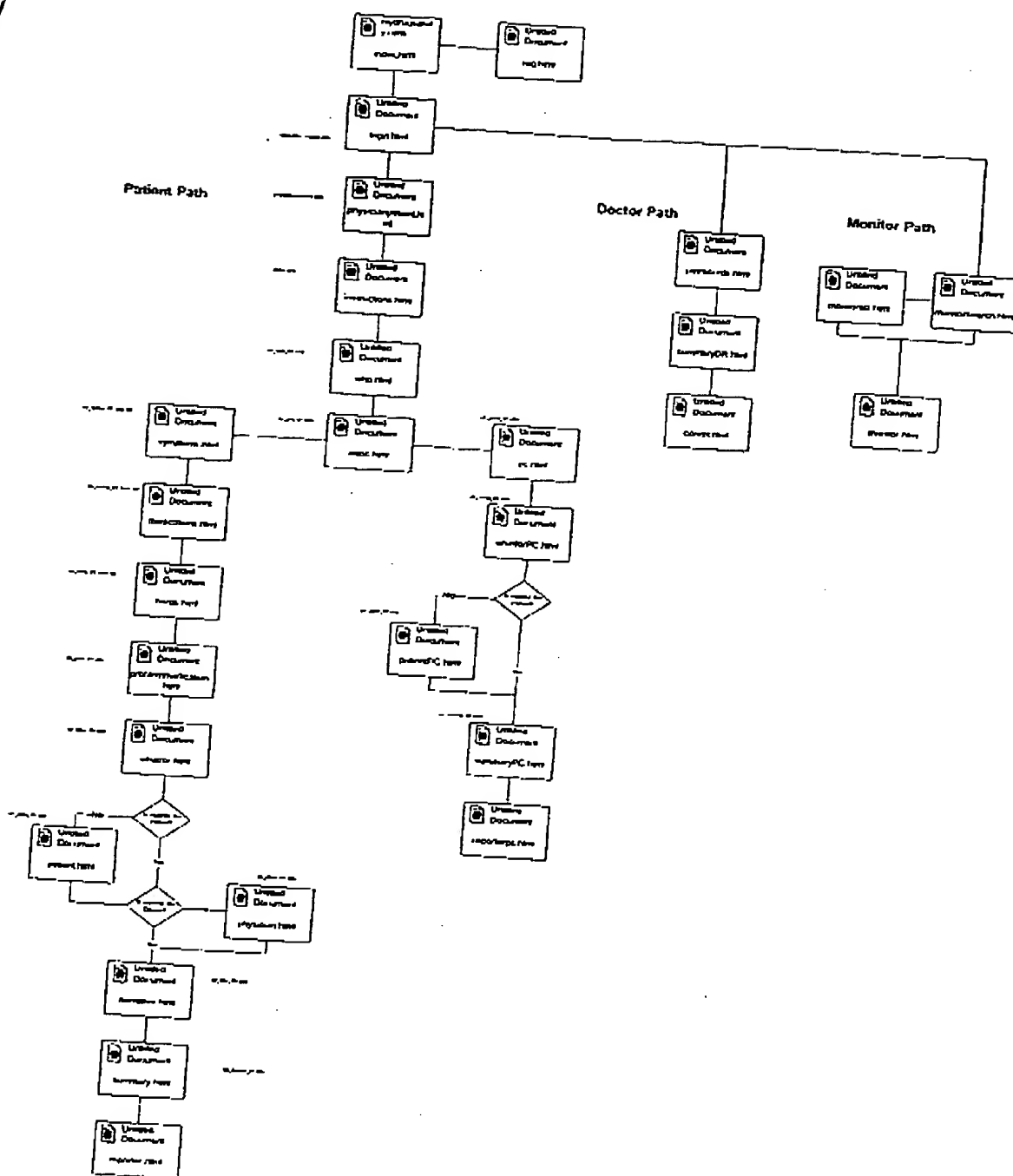


FIG. 3



Portal Pilot Workflow

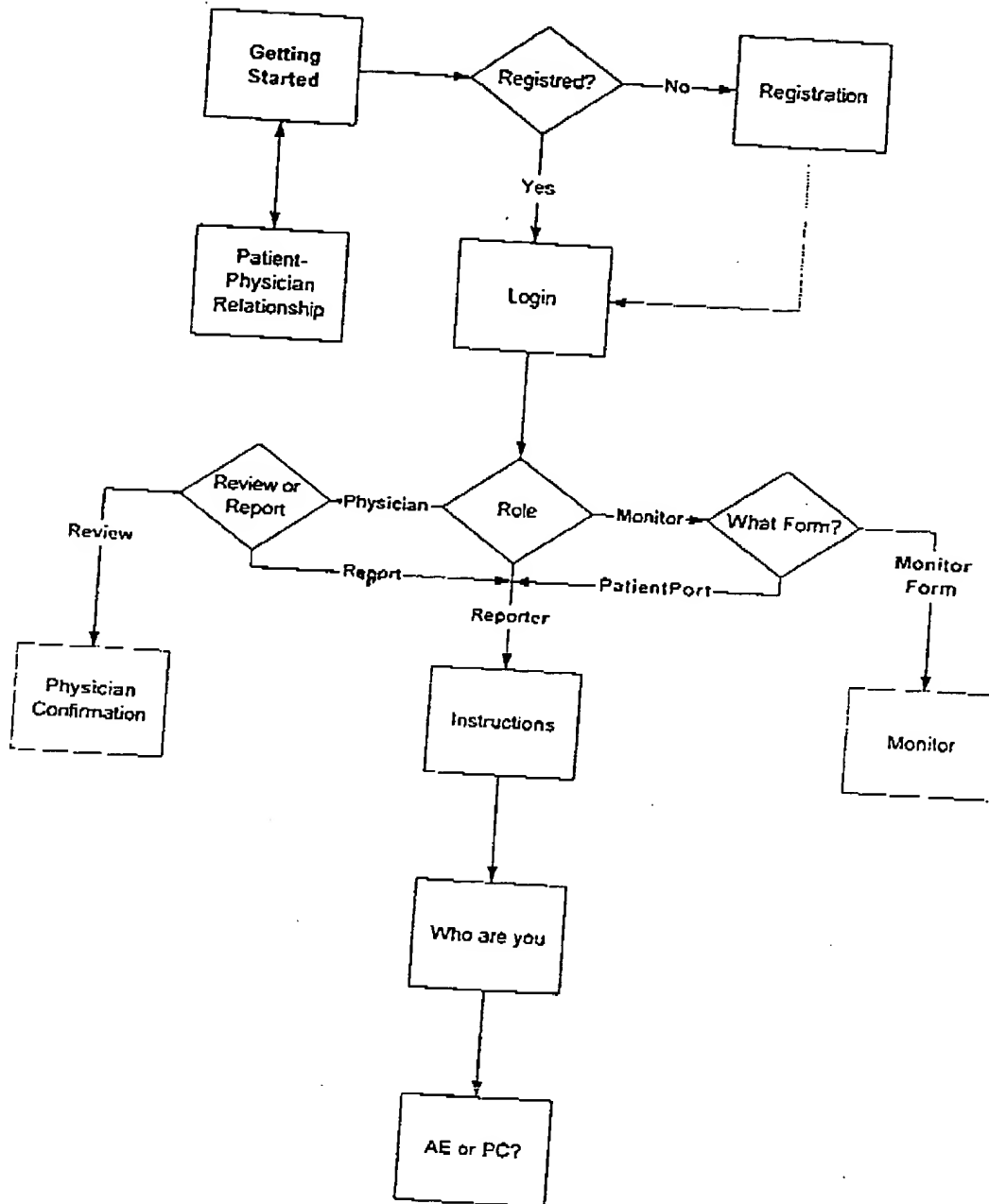
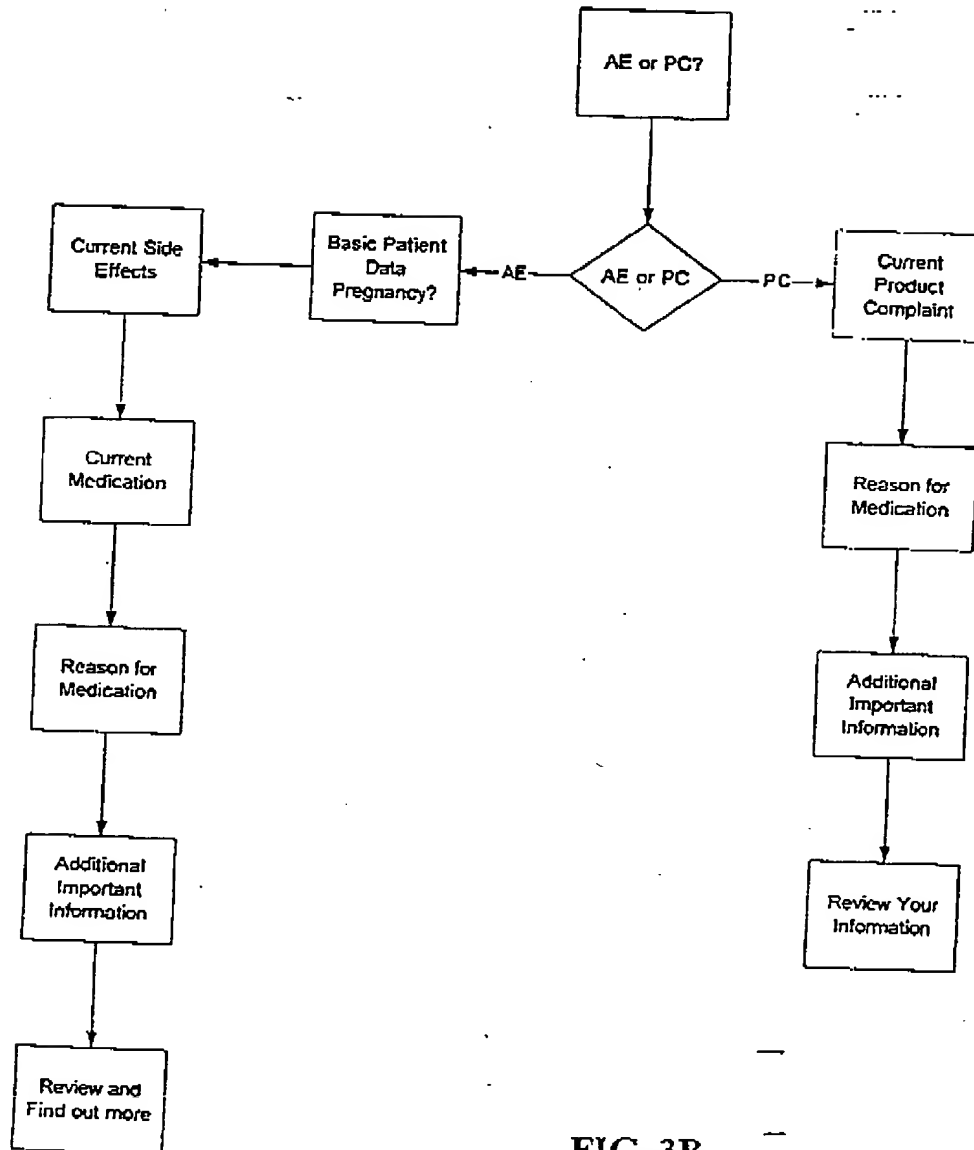


FIG. 3A



AE or PC Guided Reporting

**FIG. 3B**



Physician Confirmation

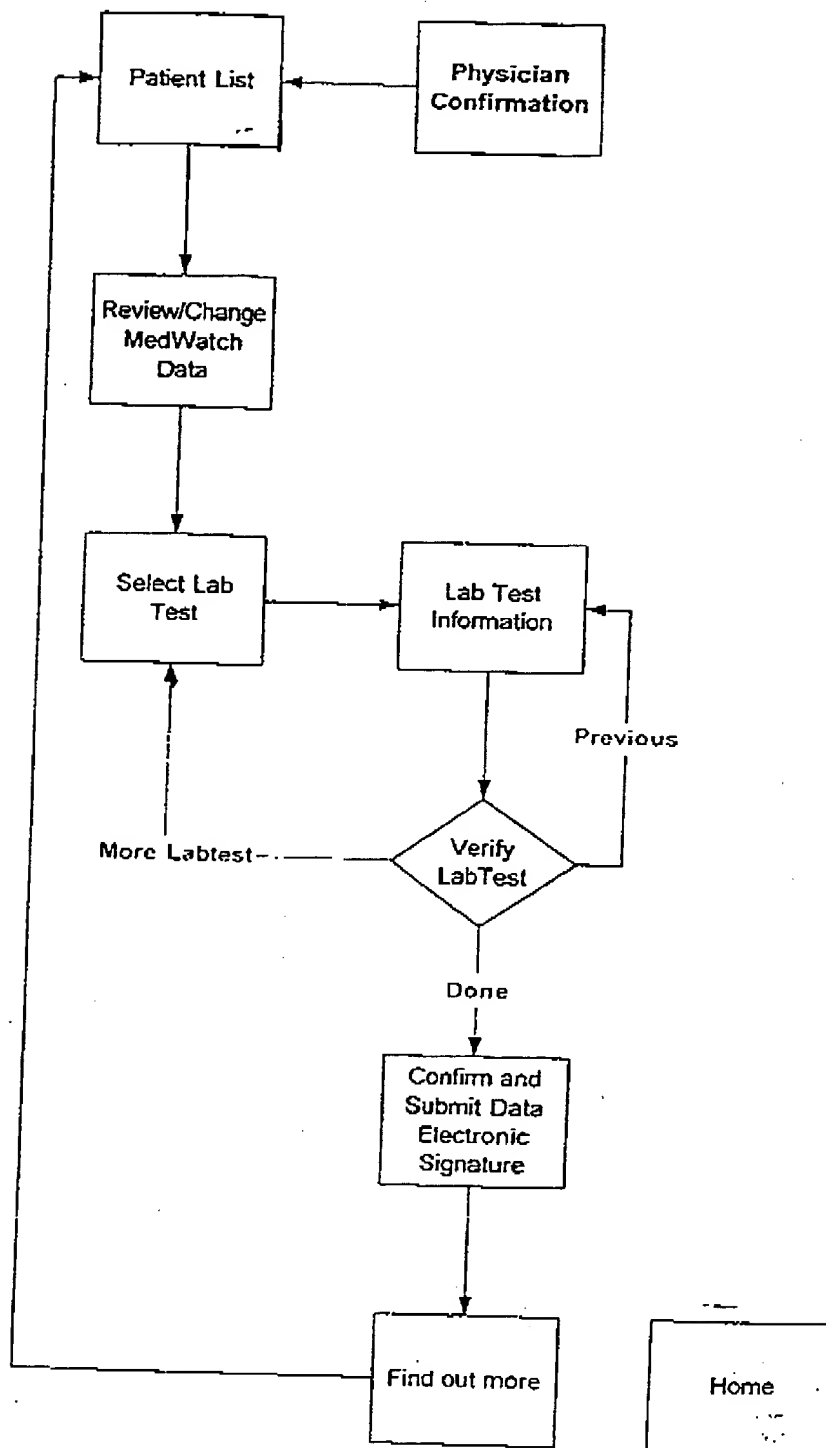


FIG. 3C



Monitor Form

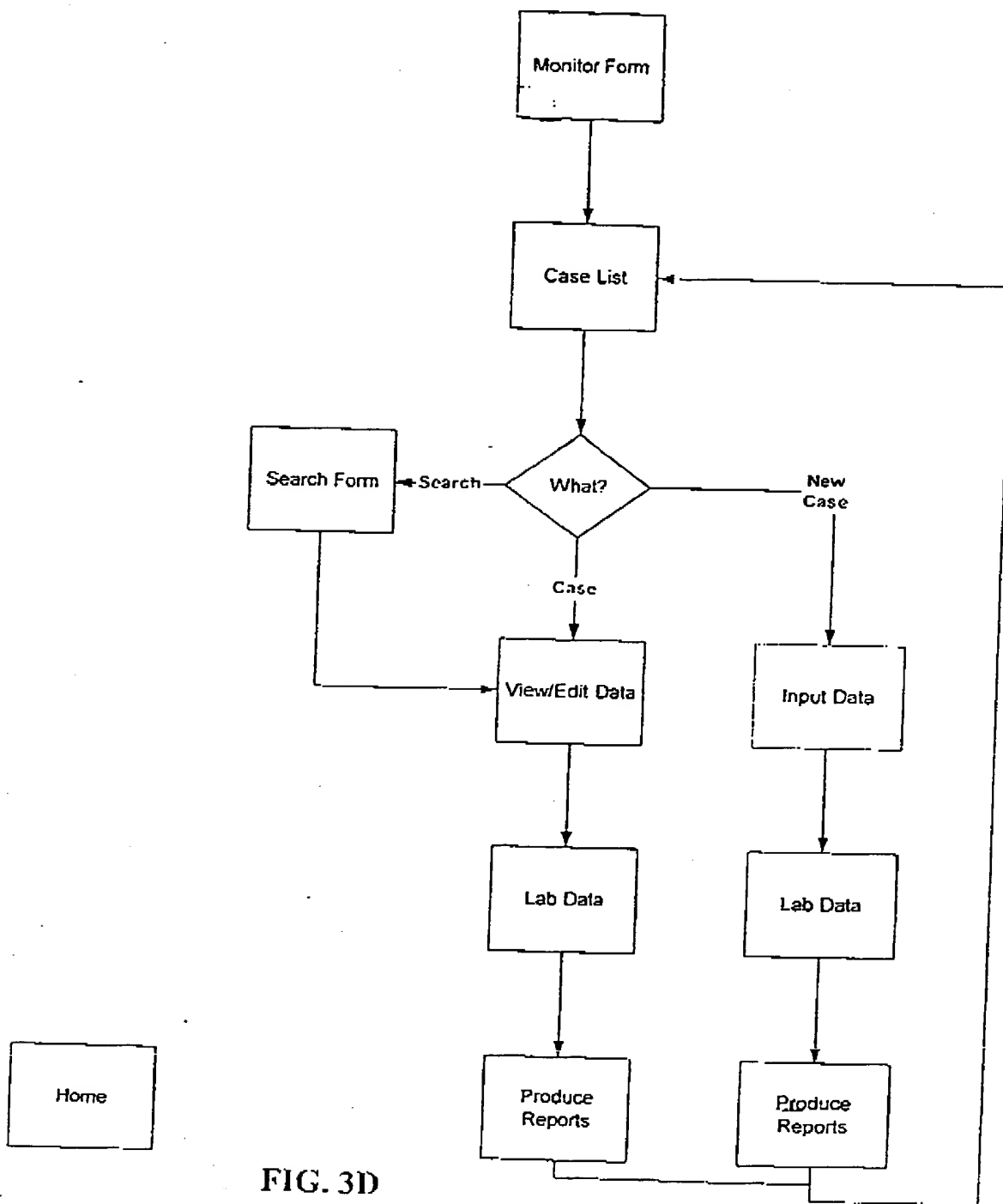
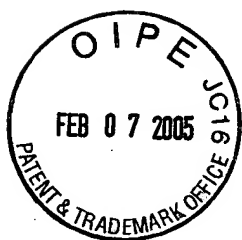


FIG. 3D



Current Side Effects

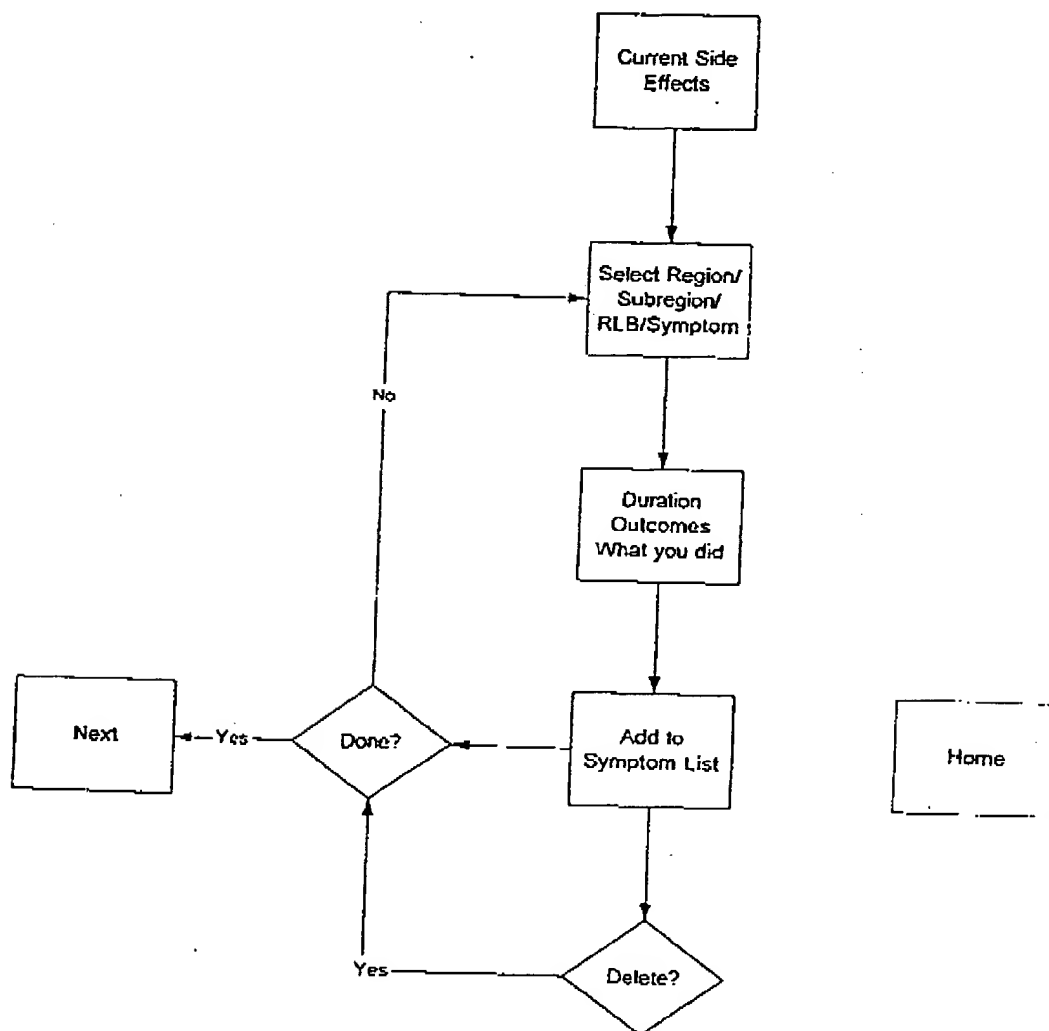


FIG. 3E



Current Medication

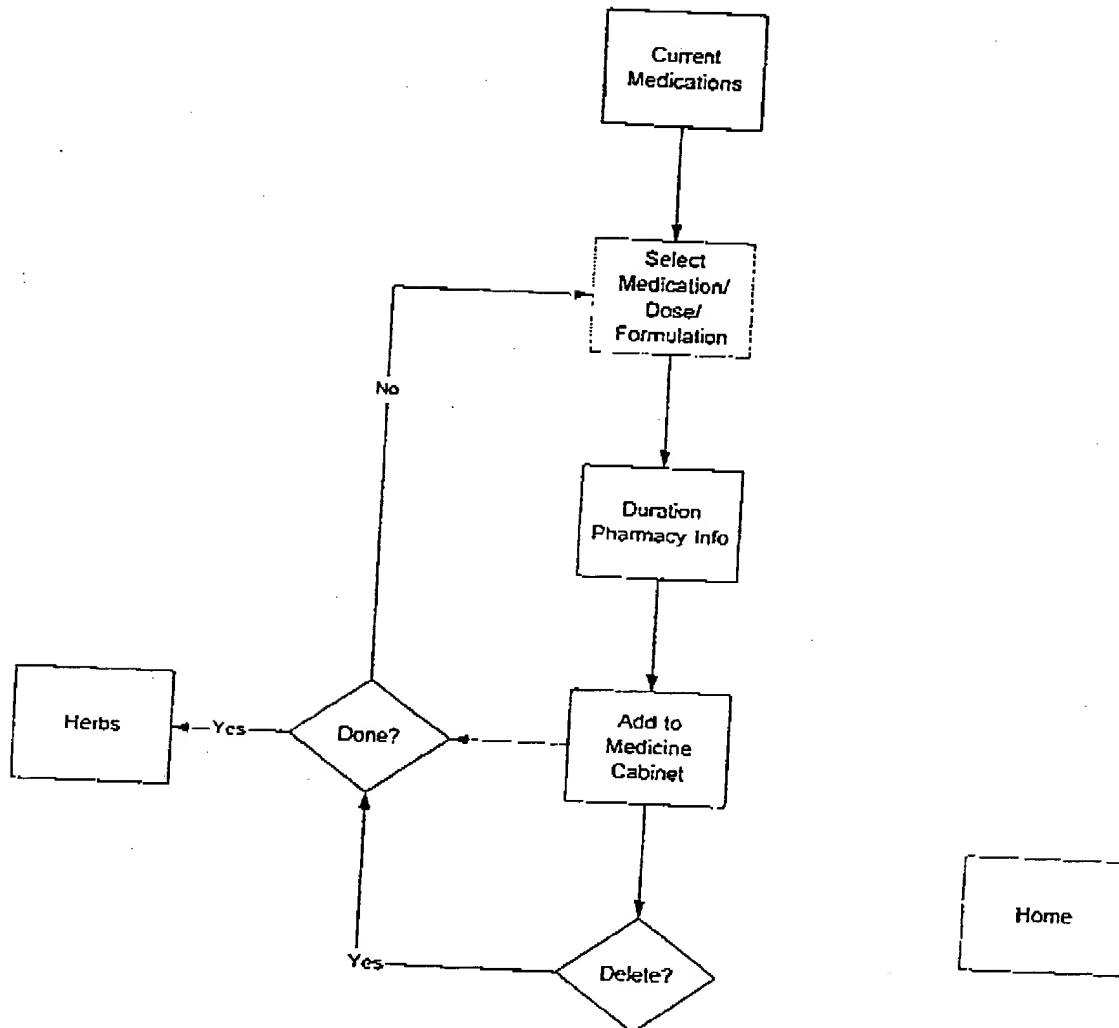


FIG. 3F



Herbs and Nutritional Supplements

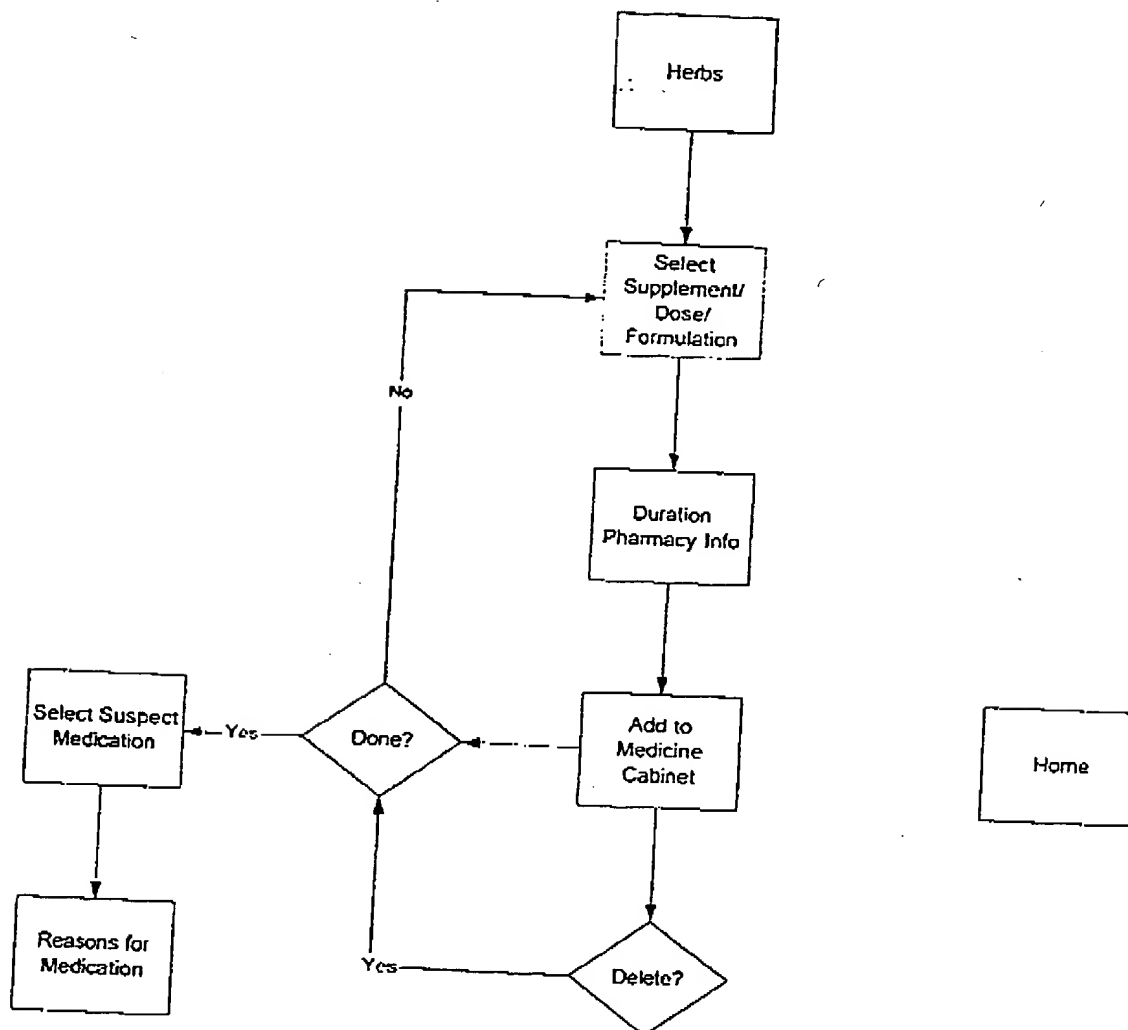
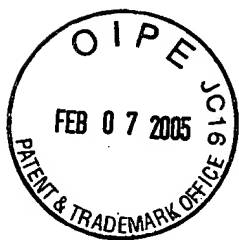


FIG. 3G



Reasons for Medication

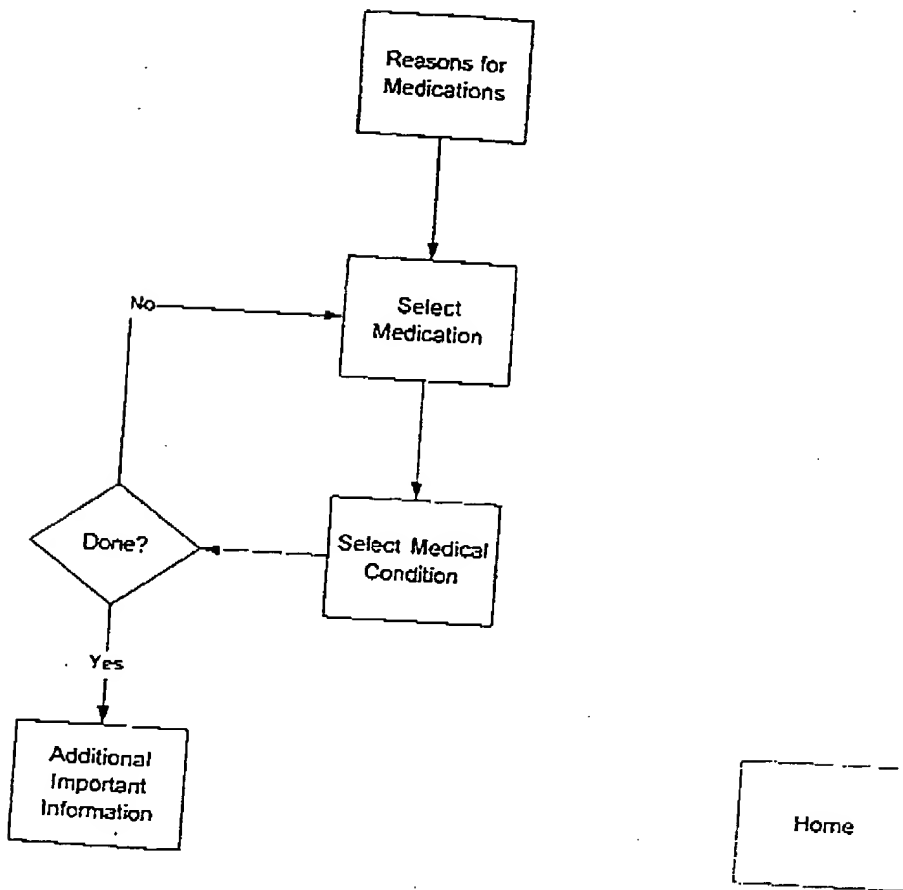


FIG. 3H



Additional Important Information

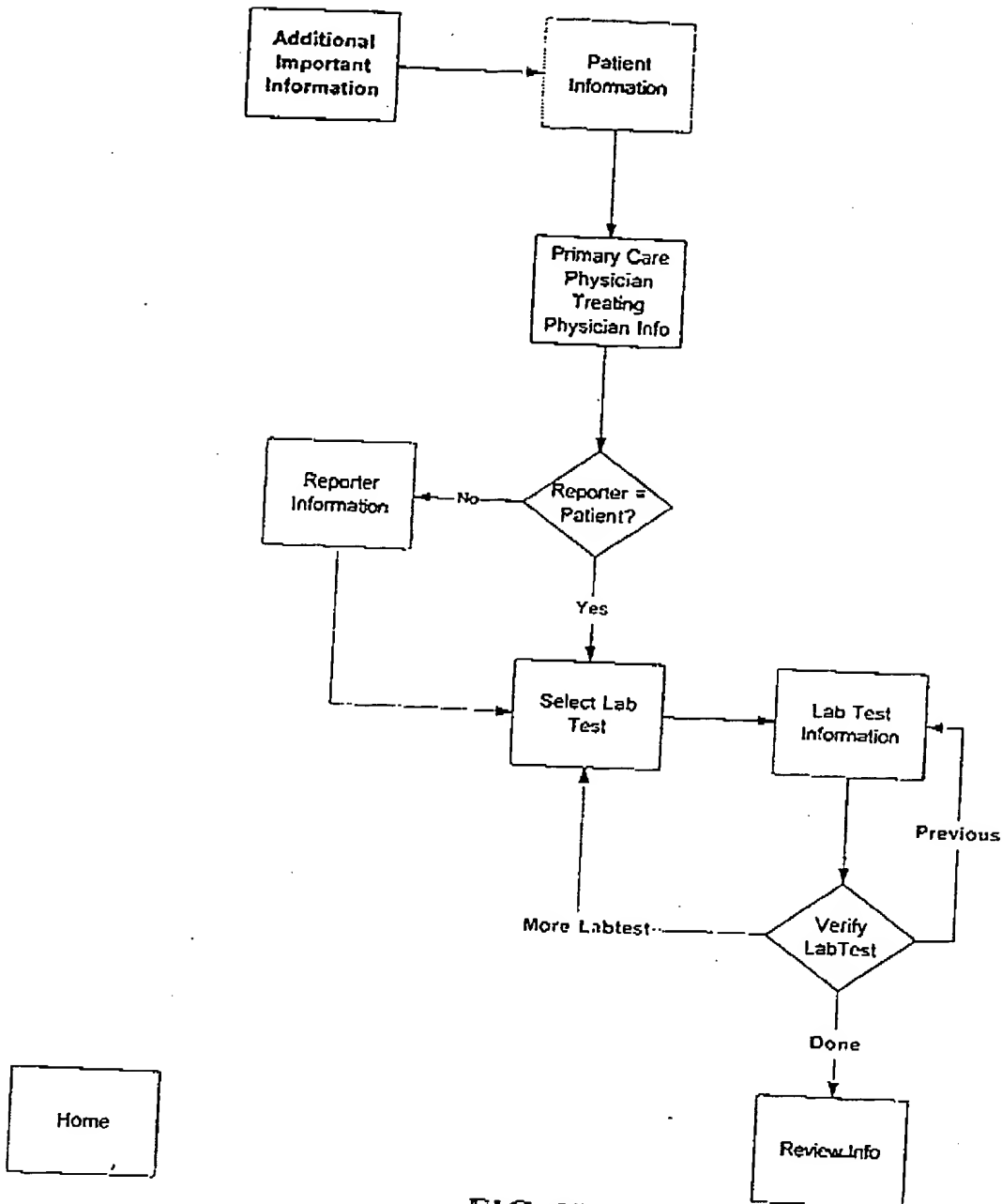


FIG. 3I



Review Information and Find out More

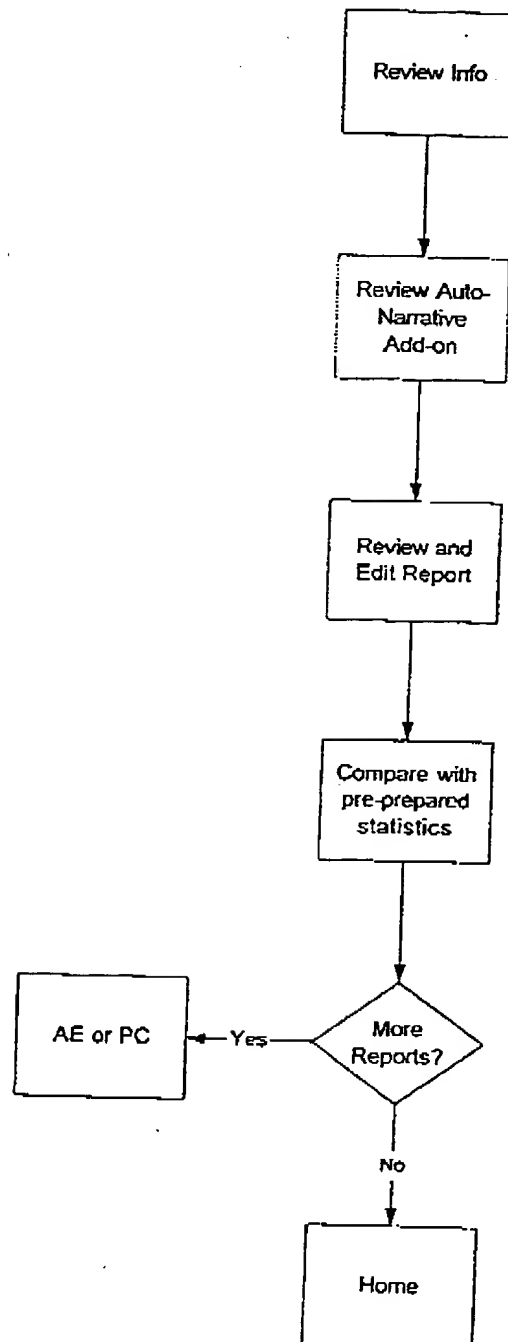


FIG. 3J



Product Complaint

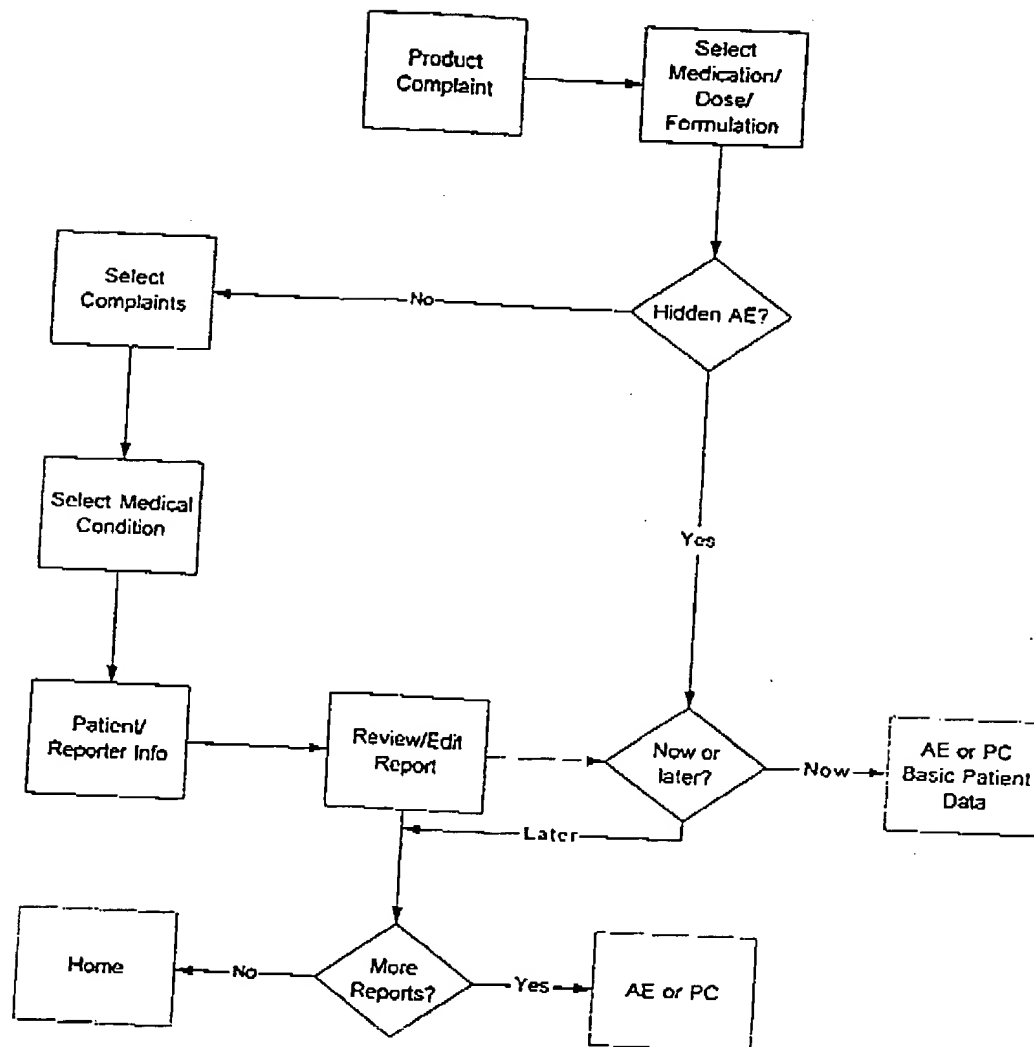


FIG. 3K



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Registration

INFORMED CONSENT

IN ORDER TO COMPLETE THE REPORT, WE MAY NEED TO CONTACT YOUR PHYSICIAN. YOUR CONSENT TO CONTACT your physician is called informed consent. Only your physician and you will see the information you provide us.

☐ Accept ☐ (required to proceed)

1 Getting Started
Login/Registration
instructions

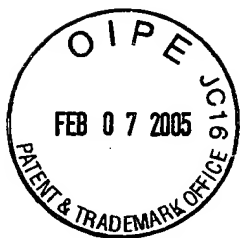
Who are you
Side Effects and/or
Product Complaints

This web portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can recreate it; 1)define a secret question (ex: What is my favorite football team) 2)define a secret answer (ex: the SF 49ers). Together these will identify you.

for this pilot, type the 8 digit registration code printed on your trial card.

First Name	<input type="text"/>
Last Name	<input type="text"/>
User ID	<input type="text"/>
Password	<input type="text"/>
Password again	<input type="text"/>
Secret Question	<input type="text"/>
Secret Answer	<input type="text"/>
Phone Number	<input type="text"/>
E-mail	<input type="text"/>

FIG. 4





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Welcome to MyDrug Safety

Getting Started

First-time user? Go to our registration page.

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easy steps. At the end, you will receive a summary report for review.

the  symbol provides online help. If you would like to read all the instructions for all the screens click here to download.

- 1 Getting Started
Login/Registration
instructions
Who are you
Side Effects and/or
Product Complaints

userID and Password 

User ID

Password

Change your Password?

New Password

Repeat Password

FIG. 5



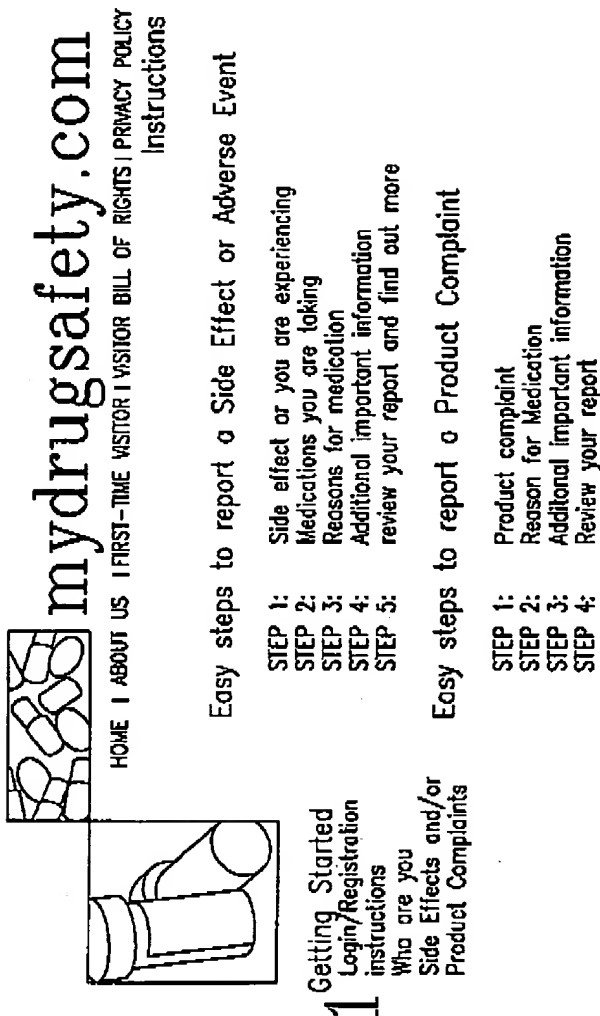
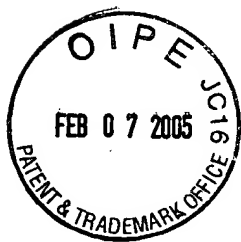
The Patient/Physician Relationship

To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

1 Getting Started
Login/Registration
instructions
Who are you
Side Effects and/or
Product Complaints

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?

FIG. 6



Next

FIG. 7



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Who Are You?

②

Getting Started
1. Login/Registration instructions
Who are you
Side Effects and/or
Product Complaints

Who Are You?

Family member/spouse
Patient
Pharmaceutical Representative

Treating Physician
Choose One

Other healthcare Professional
Choose One

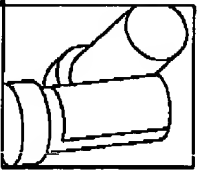
Someone else? Who?

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FIG. 8

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Adverse Event or Product Complaint?

What Do you Want to Report? ?

☐ AE ☐ PC

Adverse Reaction or a Side Effect you are having

Complaint about your medication

1 Getting Started
Login/Registration
Instructions

Who are you
Side Effects and/or
Product Complaints

Family Members Data:

Date of Birth -- (mm-dd-yyyy)

or Age

Height feet inches
(ex: 5 feet 2 inches)

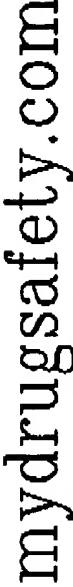
Weight lbs

Male Female
Pregnant ☒ YES

next

FIG. 9



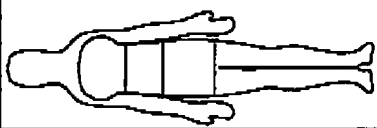


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Adverse Event
define a Symptom

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

Click the region where the symptoms occur.



or

REGION Which area?;

- Anus
- Bladder
- Buttocks
- Cervix
- Groin
- Labia Minora/Majora
- Ovaries
- Rectum
- Uterus
- Vagina

?

To delete a symptom from highlight it and press **Delete**. Only when you have finished describing all your symptoms press **Done**.

1 Getting Started

2 Current Side Effects

What Symptoms

When Started

Ended

What Result

What you did

3 Current Medications


4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

FIG. 10a





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Adverse Event
define a Symptom

Describe your adverse event. Click on a body region and a list of its subregions will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

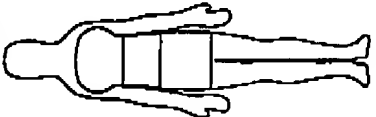
<p>Click the region where the symptoms occur.</p> <div style="text-align: center;">  <p>or</p> </div>	<p>REGION Which area?:</p> <p>Right-Buttocks Left-Buttocks Both-Buttocks</p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> </div> <p>To delete a symptom from highlight it and press Delete. Only when you have finished describing all your symptoms press Done.</p>
---	---	--

FIG. 10b

- 1 Getting Started
- 2 Current Side Effects
 - What Symptoms
 - When Started
 - Ended
 - What Result
 - What you did
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

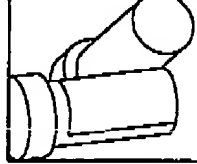


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Adverse Event
define a Symptom

FIG. 10c



1 Getting Started

2 Current Side Effects

What Symptoms
When Started
What Result
What you did

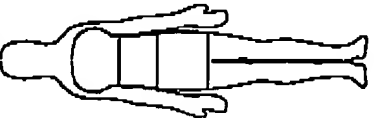
3 Current Medications

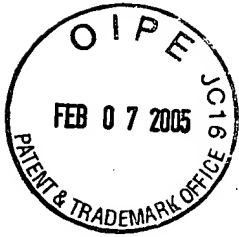
4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

Click the region where the symptoms occur.	REGION Which area?	SYMPTOM What symptom?	When did it start? (mm-dd-yyyy) When did it end (mm-dd-yyyy) OR How Long did it last? YEAR MONTH DAY It is still there? <input type="checkbox"/> yes <input type="checkbox"/> no RESULT What was the result of this event? <input type="checkbox"/> Hospitalized under 24 Hours <input type="checkbox"/> Hospitalized over 24 Hours <input type="checkbox"/> Disability	To delete a symptom from highlight it and press Only when you have finished describing all your symptoms press
	Buttocks	Hip Pain	<input type="checkbox"/> Did nothing <input type="checkbox"/> Consulted a Physician <input type="checkbox"/> Stopped Medication <input type="checkbox"/> Reduced dose to <input type="text"/> <input type="checkbox"/> Switched Medication to <input type="text"/> <input type="checkbox"/> Did it help? <input type="checkbox"/> Took medication again and effect came back <input type="checkbox"/> Took something for it. What? <input type="text"/>	<input type="button" value="Delete"/> <input type="button" value="Done"/>



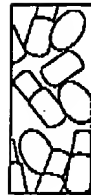
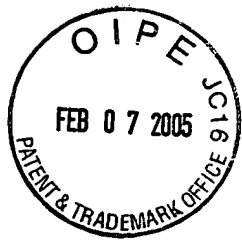
General Body		<input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Intervention Needed <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Died <input type="checkbox"/> (mm-day-yyyy) Other <input type="checkbox"/>	Did it help? <input type="checkbox"/> YES Did something else <input type="text"/>	Add Symptom to list

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{helpscreens}

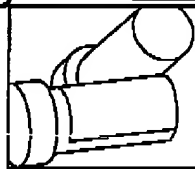
FIG. 10d



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What Medication Are You Taking?
Medication

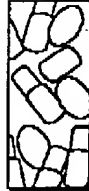
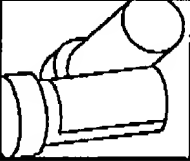


- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
 - Medications
 - Herbs and Supplements
 - suspect Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

<p>mydrugsafety.com</p> <p>HOME ABOUT US FIRST-TIME VISITOR VISITOR BILL OF RIGHTS PRIVACY POLICY</p> <p>What Medication Are You Taking? Medication</p>		<p>Your medicine Cabinet</p> <p><input type="text"/></p> <p><input type="button" value="Delete"/> <input type="button" value="Done"/></p> <p>To delete a medication from the list highlight it and press when your current Medication list is complete press</p>
<p>Medication: Lamisil</p> <p>Dose: 1%</p> <p>Formulation: CREAM</p> <p>Frequency: 0 times a Day</p>	<p>How Long</p> <p><input type="text"/> YEAR <input type="text"/></p> <p>Start <input type="text"/> (mm-dd-yyyy)</p> <p>End <input type="text"/> (mm-dd-yyyy)</p> <p>Still on it optional info</p> <p>Lot # of drug? if present <input type="text"/></p> <p>What Pharmacy did you purchase it at? <input type="text"/></p> <p>Name <input type="text"/></p> <p>Zipcode <input type="text"/></p> <p><input type="button" value="Add to Medicine Cabinet"/></p>	

FIG. 11



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What Medication Are You Taking?
Suspect Medication

Please select the medication(s) that you think may have caused the event?		?
Your Current Medications Are <input checked="" type="checkbox"/> Lamisil		
Previous	Next	

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medication
Herbs and Supplements
suspect Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

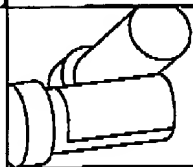
FIG. 12



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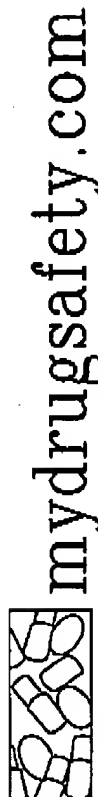
What Medication Are You Taking?
Herbs or Nutritional Supplements



- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
Medications
Herbs and Supplements
Problem Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

<p>?</p> <p>Your Current Herbs</p> <p>Your Current Medications &medicinel &medicinel</p>		<p>Add to Medicine Cabinet</p> <p>Need To delete a medication from your current list? Highlight it and press Delete</p> <p>when your current medication list is complete press Done</p>	
<p>Tell us what herbs or other supplements you are taking. click letter to choose from list. ABCDEFGHIJKLM NOPQRSTUVWXYZ</p> <p>Pick one:</p> <p>Select a medication 1</p> <p>Not on the list? Enter below</p> <p>What Dose</p> <p>Select a dose 1</p> <p>Times a day 1</p> <p>What Formulation?</p> <p>what formulation 1</p>		<p>HOW LONG</p> <p><input type="checkbox"/> number of days 1</p> <p>Start mm-dd-yy</p> <p>End mm-dd-yy</p> <p><input type="checkbox"/> Still on it optional info</p> <p>Lot # of supplement? if present</p> <p>What Pharmacy did you purchase it at?</p> <p>name</p> <p>zipcode</p>	

FIG. 13



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Adverse Event

What Are You Taking Your Medication For?

What condition are you taking your medication for? click on your medication and a list of its associated condition/disease will appear. select the appropriate one. Repeat for each medicine in the list.

Your Medication List				Medical Condition
Medication	Formulation	Dose	Frequency (Times a day)	
Lamisil	Cream	1%	4	<div>Select only one</div> <div>Not on this list?...Enter below</div> <div></div>

Previous

Next

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

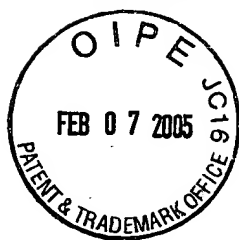
Help

{helpscreens}

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FIG. 14A



PatientPort

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Adverse Event
Lab Results

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information
Patient Information
Physician Information
Lab Test Results

6 Review Info & Find Out More

Tell us what tests were done.

Click letter to choose from list.

Then Select the appropriate test and method for the specimen. Standard values for the test will be presented with an indicator for whether the patient values are within range or out of range.

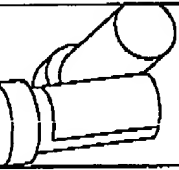
?

ABCDEFGHIJKLMN O PQRSTU VWXYZ

Test	Specimen	Method	Min-Max	test Value	Measurement Time & Date	Status of Test
Albumin	Serum	Colimentry	3.5-5.0 g/dl	dd g/dl time mm mm year	<input type="radio"/> Multiple test values at this date?	<input type="radio"/>
Aldolase				dd g/dl time mm mm year	<input type="radio"/> Multiple test values at this date?	<input type="radio"/>
Aldosterone				dd g/dl time mm mm year	<input type="radio"/> Multiple test values at this date?	<input type="radio"/>
Alkaline				dd g/dl time mm mm year	<input type="radio"/> Multiple test values at this date?	<input type="radio"/>
Phosphatase				dd g/dl time mm mm year	<input type="radio"/> Multiple test values at this date?	<input type="radio"/>

Next

FIG. 14b



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Adverse Event Product Complaint
Check your record

this Report

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More
 - Review narrative
 - Review Your Info
 - Other Similar Reports to the FDA

1			2
<p>A -30year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking lamisil 1% CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing], for [indication/condition], reportedly experienced an event [verbalim or reported] term/symptom (R/L/B) on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].</p> <p>The patient was also taking [prescription medication, over-the-counter or nutritional products; concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long</p>			

Anything to add?

1		2
<p>Blablabla</p>		


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FIG. 15



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 Review Your & Who Record
 Summary Report
 pat1 patlast

?

Review and Edit your report,

Report is complete

Type over text to edit and only when complete press
 A. Patient Information

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Review narrative
 Review Your Info
 Other Similar Reports
 to the FDA

Patient Name pat1 patlast

Date of Birth 06-16-70

Age at Event -30

Gender O Male O Female

Pregnant? O Yes O No O Unknown

Weight 110 Lbs

Height 51 feet 61 inches

(ex: 5 feet 2 inches)

A. Adverse Event Results

☐ Died On (mm-day-yyyy)☐ Hospitalized Less than 24 Hrs☐ Hospitalized over 24 Hrs☒ Disability☐ Congenital Anomaly☐ Intervention needed☐ Life threatening☐ Other

Date of Event (mm-dd-yyyy)

Date of Report 01-23-2001 (mm-dd-yyyy)

FIG. 16a



Description			
Event Abated?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown		
Event Reappeared?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown		
C. Suspect Medications			
Drug Name		Therapy Dates/Duration	Reason:
Lamisil		From 07-01-2000 to 01-01-2001 Duration: 1	Disease 2
		Dose	
		1%	
D. Concomitant Medication			
Drug Name		Therapy Dates/Duration	Reason
		Dose	

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Help

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{helpscreens}
```

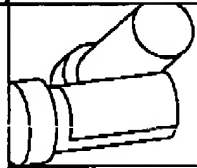
FIG. 16b



PatientPort

HOME | Wer wir sind | Erstmaliger Benutzer | Datenschutz | Logout

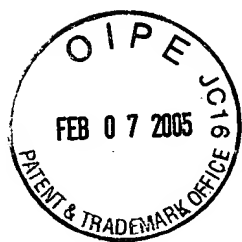
Arzneimittel-Nebenwirkungen definieren Sie Das Symptom



- 1 **Start**
Login/Registrierung
Bedienungsanleitung
wer sind Sie?
Arzneimittel-
Nebenwirkung oder
Beschwerde über das
Arzneimittel
- 2 **Arzneimittel-
Nebenwirkung**
Ihre Symptome
Beginn und Ende
Direkte Auswirkungen
Gegenreaktionen
- 3 **Ihre
Medikamente**
Medikamente
Andere Medikamente
Heilkräuter & Vitamine
Weshalb
nehmen Sie
- 4 **Weshalb
nehmen Sie**

FIG. 16C

<p>Wir bitten Sie, im folgenden Ihre Arzneimittel-Nebenwirkungen zu Beschreiben. Klicken Sie bitte eine Körperregion an und es wird eine Liste von Sub-Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein Symptom aus der präsentierten Liste auswählen. Durch Anklicken der Figur können Sie nachher weitere Regionen auswählen.</p> <p>Klicken Sie bitte die Region, in der Ihr Symptom sich aussart.</p>		<p>KOPF Wählen Sie die Region:</p>	<p>SYMPTOM Ihr Symptom</p>	<p>DAUER</p> <p>Beginn des Symptoms mm-dd-yy Ende des Symptoms mm-dd-yy Wie lange dauerte es? Tage 1 Besteht das Symptom immer noch? <input type="checkbox"/> JA</p>	<p>WAS UNTERNAHMEN SIE DAGEGEN?</p> <p><input type="checkbox"/> Nichts <input type="checkbox"/> Konsultierte einen Arzt <input type="checkbox"/> Stopppte die medikamenten Einnahme Reduzierte die medikamenten Dosis auf <input type="checkbox"/> Wechselte das Medikament auf</p>
<p>Wir bitten Sie, im folgenden Ihre Symptome Augen, verschwommene Sicht Augen, verengte Pupillen</p> <p>Um ein Symptom zu löschen, markieren Sie "LOSCHEN" Ent wenn Sie die Ihre Symptome abschließend beschrieben haben, drücken Sie bitte "FERTIG"</p>		<p>VERENGTE PUPILLEN</p>			
<p>AUGEN</p>		<p>AUSWIRKUNG DES SYMPTOMS Halte das symptom direkte medizinische Auswirkungen, wie</p>			



Hospitalisierung unter 24 Std?	Nahm ein Gegenmittel. Was?
SYMPTOM ZUR LISTE HINZUFÜGEN	

5 Zusätzliche
Informationen
patienten daten
Arzte-Daten

**6 Bestätigen
Sie Ihre Daten
Ihr generierter Bericht
Alle Ihre Daten
Vergleich mit anderen
Berichten der FDA**

FIG. 16d

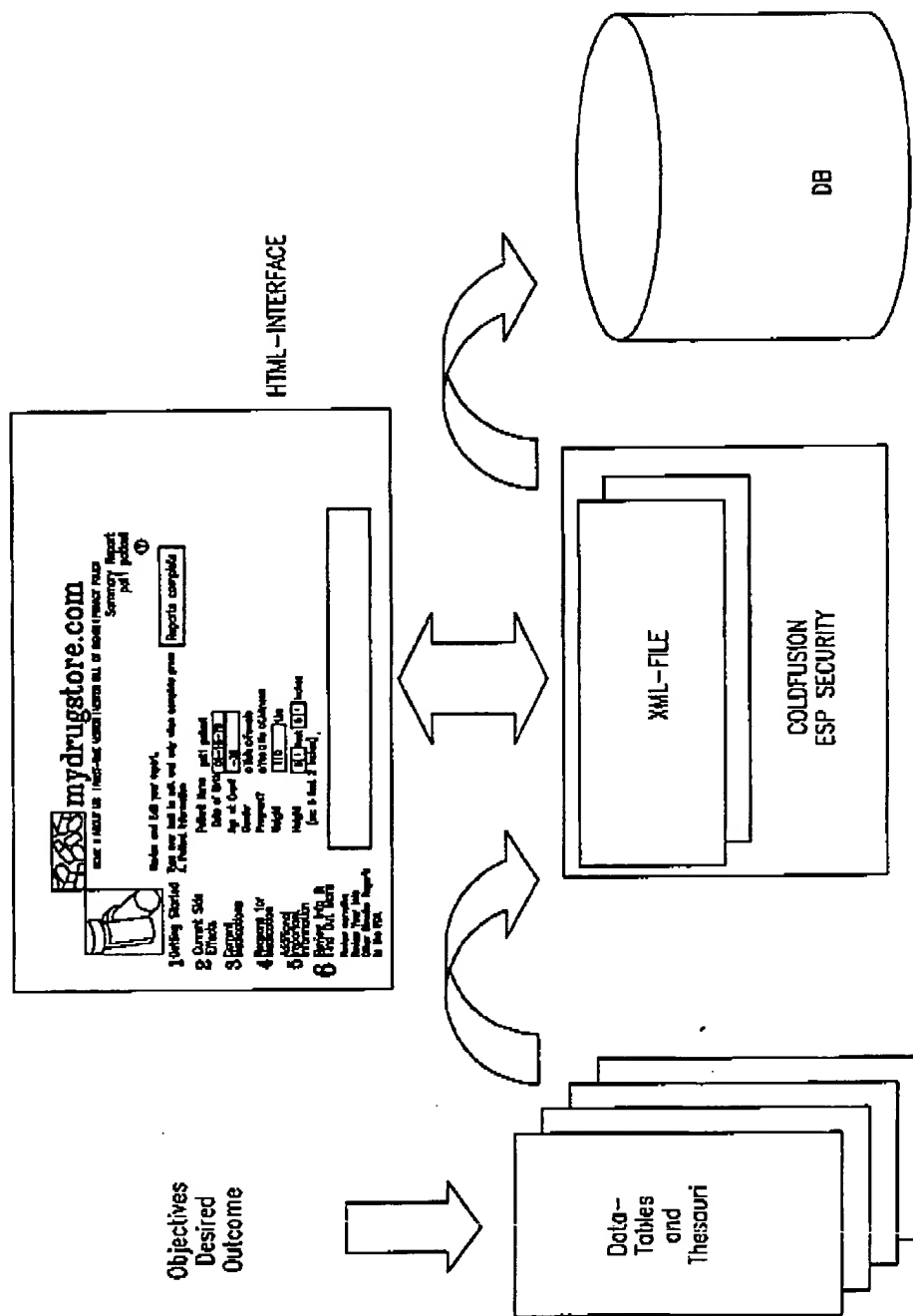
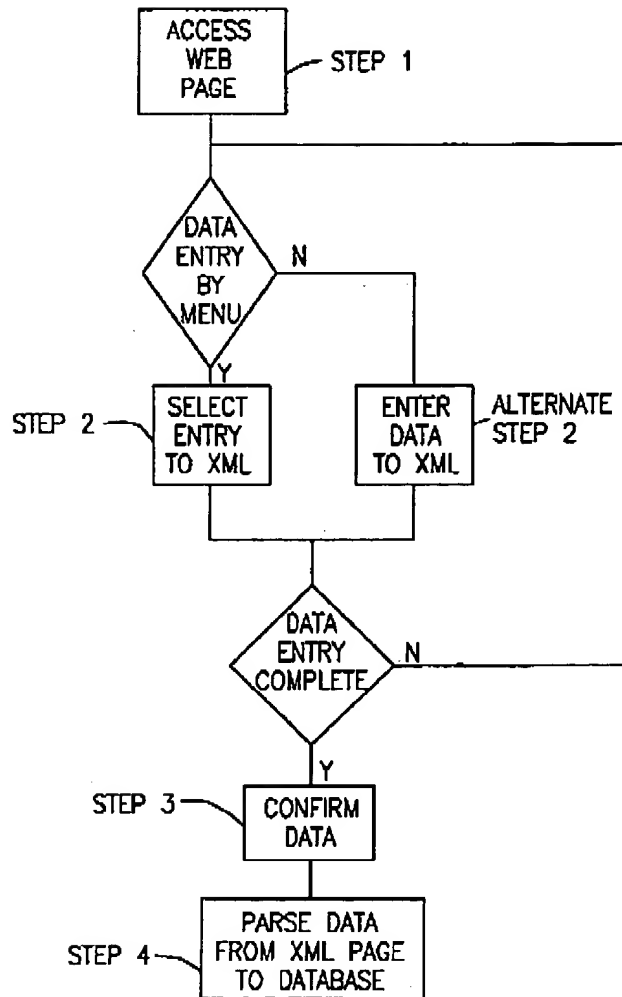


FIG. 17

*FIG. 18*